UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,409	01/18/2002	Susumu Maruo	Q68143	2146

23373 7590 07/08/2003

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20037

EXAMINER
SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,409	MARUO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01-18-02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (3 months), the Amendment and the Information Disclosure Statement, all filed 04/24/03 is acknowledged.

The 35 U.S.C. 112 second paragraph rejections have been withdrawn.

Claims 1-12 are pending. Claims 4-7 and 10-11 have been amended. Claims 1-12 remain rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda *et al.* (US Pat. No. 5, 045,553).

Ueda discloses a pharmaceutical composition for percutaneous drug absorbtion and percutaneous drug absorbtion promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA)

support film is 50 microns (see reference col. 7, lines 15-20 – Example 12). The gel patch preparation can further include an acrylic adhesive layer on the film (col. 7, lines 15-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (US Pat. No. 5, 045,553).

Ueda teaches a pharmaceutical composition for percutaneous drug absorbtion and percutaneous drug absorbtion promoter comprising a patch preparation comprising

a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (see reference col. 7, lines 15-20 – Example 12). The gel patch preparation can further include an acrylic adhesive layer on the film (col. 7, lines 15-45). Ueda teaches that the pharmaceutical composition can be administered in various dosage forms. When the composition is in the form of a patch, the composition is spread over a support member (col. 3, lines 43-55). The composition may also be made up into ointments, such as Macrogol ointments, FAPG ointments, hydrophilic ointments, absorptive ointments, Carbopol gel ointments, etc (col. 3, lines 64-68). It is also possible to fill the composition in an appropriate container (to prevent adherence to clothes) and attach the container to the skin so that the composition can come into contact therewith or to coat a support member (as in tape preparations) with the composition to a certain thickness and apply the whole to the skin (col. 4, lines 9). Furthermore, the composition can be made up into patches, for example, by spreading the composition over an appropriate support member (i.e., made of aluminum), and if necessary sealing with an absorption promoter film such as ethylene-vinyl acetate copolymer film (col. 4, lines 10-20). The Examples on cols. 7-9 further demonstrate the use of patch preparations comprising a support member and a gel (ointment) in various percentages, which read on the applicant's instantly claimed ranges.

Ueda while teaching a pharmaceutical composition for percutaneous drug absorbtion and percutaneous drug absorbtion promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum

support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (col. 7, lines 15-20 – Example 12), does not explicitly teach the degree of water vapor permeability of the support. It would have been deemed obvious to one of ordinary skill in the art at the time the invention was made and in the absence of showing the criticality of the instantly claimed vapor permeability range, suitable amounts or ranges of water vapor permeability could be determined through routine or manipulative experimentation.

Response to Arguments

Applicant's arguments filed 04/24/03 have been fully considered but they are not persuasive.

Firstly, the applicant argued regarding the 35 U.S.C. 102(b) rejection of claims 1 and 6, stating, "Ueda et al does not disclose or suggest the characteristics of the support member as presently claimed, i.e., the thickness of 1-2000 microns and 50% modulus of 5-600 g/cm."

This argument has been fully considered, but was not found to be persuasive. Ueda disclose a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorbtion promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (col. 7, lines 15-20 – Example 12). The examiner notes that

the ethylene vinyl acetate is, in itself, also a support member or support film, as is the aluminum, for instance. Ueda also disclose that the support member can be made of cloth. The applicant's argument that the thickness or modulus of the support is not suggested, is not persuasive since Ueda clearly teaches a patch preparation for percutaneous administration whereby the pharmaceutical composition can coat a support member with said composition to a certain thickness and apply the whole to the skin so that said composition can come into contact therewith (col. 4, lines 1-9). The prior art teaches a similar formulation comprising similar ingredients as instantly claimed for the same intended purpose.

Secondly, the applicant argued regarding the 35 U.S.C. 103(a) rejection of claims 1-12, stating "The examiner has not established a prima facie case of obviousness over Ueda et al. Ueda does not disclose a support member of specific characteristics as presently claimed. There is no indication in Ueda that use of a support with these specific properties would improve percutaneous absorption of an active ingredient, which was the main objective of Ueda et al."

These arguments have been fully considered, but were not found to be persuasive. Ueda discloses a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support. The percentages taught by Ueda fall within the applicant's claimed ranges. One of ordinary skill would determine suitable ranges or percentages through routine or manipulative experimentation to obtain the best possible results. Furthermore, generally differences

in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. There is no significant distinction observed between the instant invention and the prior art since the prior art teaches an ointment preparation whereby the patch markedly promotes percutaneous absorption.

Lastly, the applicant argued, "The ointment patch of the present invention can prevent transfer of ointment elsewhere as well as reduction in its drug releasing ability, without causing uncomfortableness when applied to skin. The present invention solved the problems encountered in Ueda et al, such as coming off when applied to joint areas, skin irritation and side effects."

These arguments have been fully considered but were not found to be persuasive. Ueda et al. at col. 4, lines 1-9, teach a patch preparation having sustained release properties, controlled drug absorption and preventing adherence to clothes wherein it is also possible to fill the composition in an appropriate container and attach the container to the skin so that the composition can come into contact therewith. One of ordinary skill in the art would be aware of overcoming or avoiding any possible discomfort given by the preparation. Furthermore, Ueda teaches that the preparation is suitable for skin and thus the preparation would not be seen as unsuitable for the purpose intended. Ueda also employs aluminum or cloth as the support, which is conventionally or routinely used in skin/patch preparations and thus would not be seen as unsuitable for use. Ueda teaches the prevention of adherence of the preparation

onto clothes and thus this would signify better adhesion or improved adhesion capabilities to the skin.

Note: The JU 3-066506 reference in the PTO-1449 has been considered, however no date was provided.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspond nc

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

July 01, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600